

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	Case No. 97-550-SLR
)	(Consolidated)
MEDTRONIC VASCULAR, INC.)	
BOSTON SCIENTIFIC CORPORATION,)	
and SCIMED LIFE SYSTEMS, INC.,)	
)	
Defendants.)	
)	
BOSTON SCIENTIFIC CORPORATION,)	
and SCIMED LIFE SYSTEMS, INC.)	
)	
Plaintiffs,)	
)	
v.)	Case No. 98-19-SLR
)	
ETHICON, INC.,)	
CORDIS CORPORATION, and)	
JOHNSON & JOHNSON)	
INTERVENTIONAL SYSTEMS CO.)	
)	
Defendants.)	
)	

BSI'S REPLY BRIEF IN SUPPORT OF ITS
RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW
AND, IN THE ALTERNATIVE, FOR A NEW TRIAL

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May 25, 2005

TABLE OF CONTENTS

	Page
INTRODUCTION.....	1
A. JMOL of Noninfringement.....	1
B. New Infringement Trial.....	1
C. JMOL of Invalidity.....	1
D. New Obviousness Trial	2
ARGUMENT	2
I. JMOL of Noninfringement Is Warranted Because Cordis's Evidence That the Individual Struts and the Starting Material of the NIR Stent Are Uniformly Thick Does Not Support the Infringement Verdict.	2
A. The Only Disputed Infringement Issue for the Jury Was to Identify the Structure on the NIR Stent That Corresponds to the "Wall Surface" of the "Tubular Member" That Is Required to Have a "Substantially Uniform Thickness."	3
B. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Flawed Because It Is Based Solely on the Example of the Preferred Embodiment Made from a Preexisting Tube of Uniform Thickness.....	4
C. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Inconsistent with the Claim Language.	5
D. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Inconsistent with Its Own Prosecution Arguments in the Reexamination.	6
E. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Inconsistent with the Federal Circuit's Decision in the Cordis-AVE Appeal.	8
F. Cordis's Criticism of BSC's Noninfringement Defense Based on the Protruding U-Loops of the NIR Stent Is Inconsistent with Cordis's Own Prosecution Arguments, with the Claim Language, and with the Federal Circuit's Decision.....	9

II.	A New Infringement Trial Is Warranted Because of Prejudicial Errors That Very Likely Affected the Verdict.....	10
A.	It Was Prejudicial Error to Instruct the Jury Wrongly During Deliberations That the “Wall Surface” Limitation Was Not In Dispute When Identifying the Structure That Corresponded to the “Wall Surface” Was Disputed and Critical to Whether the “Substantially Uniform Thickness” Limitation Was Met.....	10
B.	It Was Reversible Error for Cordis to Treat Undesignated Impeachment Deposition Testimony as Substantive Evidence to Mislead the Jury into Believing That BSC Had Admitted Infringement.....	12
III.	JMOL of Invalidity Is Warranted Because Cordis’s Evidence of the Nonobviousness of the Intraluminal Method Was Legally Irrelevant and Does Not Support the Verdict, and BSC’s Evidence of the Obviousness of the Claimed Device Was Clear and Convincing and Not Challenged by Cordis	14
A.	The Validity of Claim 23 Depends on the Nonobviousness of the Claimed Structure Because the Claim Is Directed to a Device, Not to a Device That Must Be Used in a Particular Method.....	15
B.	Cordis’s Evidence Does Not Support the Verdict Because It Does Not Relate to the Nonobviousness of the Structure of the Claimed Device.....	16
IV.	A New Obviousness Trial Is Warranted Because of Prejudicial Errors That Very Likely Affected the Verdict.....	18
A.	It Was Prejudicial Error to Prevent BSC from Addressing the Method Claims to Which Cordis’s Nonobviousness Evidence Was Related.....	18
B.	It Was Prejudicial Error to Prevent BSC from Rebutting Any Nexus Between Cordis’s Evidence About Industry Success and the Rigid Claimed Stent with Cordis’s Admission During “Project Olive” about the Key Importance of Flexibility.....	18
C.	It Was Prejudicial Error to Permit Cordis to Treat Admittedly Misleading Impeachment Material as Substantive Evidence to Mislead the Jury into Believing That the Ersek Sleeve Is Like a “Stapler.”.....	19
	CONCLUSION	20

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>AFG Indus., Inc. v. Cardinal IG Co.,</i> 375 F.3d 1367 (Fed. Cir. 2004).....	9
<i>Allen Archery, Inc. v. Browning Mfg. Co.,</i> 819 F.2d 1087 (Fed. Cir. 1987).....	15
<i>Ayoub v. H.N. Spencer,</i> 550 F.2d 164 (3d Cir. 1977).....	14, 20
<i>Bankers Trust Co. v. Bethlehem Steel Corp.,</i> 761 F.2d 943 (3d Cir. 1985).....	9
<i>Beck v. Haik,</i> 377 F.3d 624 (6th Cir. 2004).....	19
<i>Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.,</i> 289 F.3d 801 (Fed. Cir. 2002).....	15, 16
<i>Coleman v. Wilson,</i> 912 F. Supp. 1282 (E.D. Cal. 1995).....	13
<i>Cordis Corp. v. Medtronic AVE, Inc.,</i> 339 F.3d 1352 (Fed. Cir. 2003).....	7, 8
<i>Corning Glass Works, Inc. v. Sumitomo Elec. USA, Inc.,</i> 868 F.2d 1251 (Fed. Cir. 1989).....	16
<i>Crowley v. Chait,</i> Civ. No. 85-2441(HAA), 2004 U.S. Dist. LEXIS 27235 (D.N.J. Dec. 27, 2004).....	13
<i>Ekchian v. Home Depot, Inc.,</i> 104 F.3d 1299 (Fed. Cir. 1997).....	7
<i>Fineman v. Armstrong World Indus., Inc.,</i> 980 F.2d 171 (3d Cir. 1992).....	14, 20
<i>Globe Savings Bank, F.S.B. v. United States,</i> 61 Fed. Cl. 91 (Ct. Cl. 2004).....	13
<i>In re Cruciferous Sprout Litig.,</i> 301 F.3d 1343 (Fed. Cir. 2002).....	15
<i>In re Gardiner,</i> 171 F.2d 313 (CCPA 1948).....	16

<i>In re Paulsen</i> , 30 F.3d 1475 (Fed. Cir. 1994)	17
<i>Mendenhall v. Cedarapids, Inc.</i> , 5 F.3d 1557 (Fed. Cir. 1993)	15
<i>Pitney-Bowes Co. v. Hewlett-Packard, Inc.</i> , 182 F.3d 1298 (Fed. Cir. 1999)	15
<i>Poly-America, L.P. v. GSE Lining Tech., Inc.</i> , 383 F.3d 1303 (Fed. Cir. 2004)	16
<i>Rowe v. Dror</i> , 112 F.3d 473 (Fed. Cir. 1997)	15
<i>Shelcore, Inc. v. Durham Indus., Inc.</i> , 745 F.2d 621 (Fed. Cir. 1984)	15
<i>Sjolund v. Musland</i> , 847 F.2d 1573 (Fed. Cir. 1988)	17
<i>Southwall Techs., Inc. v. Cardinal IG Co.</i> , 54 F.3d 1570 (Fed. Cir. 1995)	7
<i>Standard Oil Co. v. American Cyanamid Co.</i> , 774 F.2d 448 (Fed. Cir. 1985)	7
<i>Stecyk v. Bell Helicopter Textron, Inc.</i> , 295 F.3d 408 (3d Cir. 2002)	19
<i>Stevenson v. Int'l Trade Comm.</i> , 612 F.2d 546 (CCPA 1979)	16
<i>Storage Tech. Corp. v. Cisco Sys., Inc.</i> , 329 F.3d 823 (Fed. Cir. 2003)	16
<i>Sutter v. Robinson</i> , 119 U.S. 530 (1886)	7
<i>Toro Co. v. Textron, Inc.</i> , 499 F. Supp. 241 (D. Del. 1980)	17
<i>Tracinda Corp. v. DaimlerChrysler AG</i> , C.A. No. 00-993-JJF, 2005 WL 730322 (D. Del. Mar. 30, 2004)	13
<i>United States v. Barber</i> , 442 F.2d 517 (3d Cir. 1971)	14, 20
<i>United States v. Quintero</i> , 38 F.3d 1317 (3d Cir. 1994)	14, 20

STATUTES

35 U.S.C. § 294 (2005).....	15
-----------------------------	----

RULES

Fed. R. Civ. P. 32 (2005).....	13
--------------------------------	----

Fed. R. Evid. 403 (2005).....	19
-------------------------------	----

Fed. R. Evid. 801 (2005).....	13
-------------------------------	----

INTRODUCTION

Cordis's answering brief confirms that the infringement and nonobviousness verdicts are not legally supported and that the trial was tainted by prejudicial errors which warrant a new trial.

A. JMOL of Noninfringement

BSC should be granted JMOL of noninfringement because Cordis's evidence that the individual struts of the NIR stent are uniformly thick, due to the uniform thickness of the starting material from which the NIR stent is made, does not legally support the verdict. Cordis's argument rests on the flawed premise that the thickness of the "wall surface" of the "tubular member" is determined by simply ascertaining the thickness of the metal struts. That is inconsistent with the claim language, with Cordis's prosecution arguments, and with the Federal Circuit's decision in the Cordis-AVE appeal, each of which define the thickness of the "wall surface" in a manner that accounts for the orientation of the struts, not just the thickness of the struts or the starting material. JMOL of noninfringement is also warranted because Cordis did not challenge BSC's evidence that the protruding U-loops on the NIR stent create thickness variations in the "wall surface" which exceed the 100% outer limit of the claim construction.

B. New Infringement Trial

If the Court does not grant JMOL of noninfringement, a new infringement trial is warranted because of prejudicial errors which very likely affected the verdict. First, it was prejudicial error to instruct the jury wrongly during deliberations that the "wall surface" limitation was not in dispute, because the correct identification of the structure on the NIR stent that corresponds to the claimed "wall surface" that is required to have a "substantially uniform thickness" was intensely disputed and critical to whether the "substantially uniform thickness" limitation was met. Second, it was reversible error for Cordis to treat undesignated out-of-context impeachment deposition testimony by Mr. Brown and Dr. Low as substantive evidence during closing arguments to mislead the jury into believing that BSC admitted infringement. Third, the verdict is against the weight of the evidence.

C. JMOL of Invalidity

BSC should be granted JMOL of invalidity for obviousness because Cordis's nonobviousness evidence does not legally support the verdict and Cordis did not challenge BSC's clear and convincing

evidence of obviousness. Cordis erected the false premise that claim 23 is directed to a device that must be used in a particular method, and offered irrelevant evidence of the nonobviousness of using the device to perform that method. The claim, however, is to a device having a particular structure, and the validity of the claim depends on the nonobviousness of that structure. Cordis's legally irrelevant evidence about the nonobviousness of intraluminally delivering and expanding a stent on a balloon as compared to the invasive surgical method of the prior art Ersek patent does not support the verdict. JMOL of invalidity is warranted because Cordis did not challenge BSC's clear and convincing evidence that the claimed device was obvious in view of the Ersek device.

D. New Obviousness Trial

Finally, if the Court does not grant JMOL of invalidity, a new obviousness trial is warranted because of prejudicial errors which very likely affected the verdict. First, it was prejudicial error to permit Cordis to present evidence about the nonobviousness of the method of intraluminal delivery covered by claims that were not in suit while preventing BSC from drawing the jury's attention to those unasserted claims. Second, it was prejudicial error to permit Cordis to proclaim that the success of the entire stent industry rested on the features of the claimed device while preventing BSC from presenting Cordis's admission during "Project Olive" that flexibility, which is not a feature of the claim, was key to that success. Third, it was prejudicial error to allow Cordis to use Dr. Ersek's curriculum vitae and out-of-context testimony by Dr. Heuser from the Cordis-AVE trial to mislead the jury into believing that, unlike Dr. Snyder, they both considered the Ersek sleeve to be like a "stapler," when, as Cordis and its counsel well knew, both of them had actually testified that they did not. Fourth, the verdict is against the weight of the evidence.

ARGUMENT

I. JMOL of Noninfringement Is Warranted Because Cordis's Evidence That the Individual Struts and the Starting Material of the NIR Stent Are Uniformly Thick Does Not Support the Infringement Verdict.

JMOL of noninfringement of claim 23 is appropriate because Cordis's evidence that the individual struts and the starting material of the NIR stent are uniformly thick does not legally support the verdict that the thickness of the "wall surface" of the "tubular member" of the NIR stent literally is

“substantially uniform.” BSC Br. 4-15.

Cordis’s infringement theory is based on a flawed premise: that the thickness of the “wall surface” of the “tubular member” of the NIR stent is simply the thickness of the metal without regard to the orientation of the metal. Cordis Br. 3-12. Cordis does not dispute that its infringement case was limited to proving the uniform thickness of the metal, *i.e.*, the thickness of each individual strut of the NIR stent and the flat sheet of starting material from which the NIR stent is made. Cordis Br. 4-5. This evidence does not legally support the infringement verdict because Cordis’s theory based on individual strut thickness is inconsistent with the claim language, with Cordis’s prosecution arguments distinguishing the prior art Ersek patent during the reexamination, and with the Federal Circuit’s decision in the Cordis-AVE appeal, each of which account for the orientation of the struts in defining the thickness of the “wall surface” of a “tubular member.” Where, as in the Ersek device and the NIR stent, the struts are twisted or protrude relative to adjacent struts, the thickness of the “wall surface” is the radial thickness of the tubular region that encompasses the orientation of the protruding struts whose outer surface defines the “wall surface,” not the thickness of the starting material or the individual struts without reference to their orientation. BSC Br. 4-15.

Under the proper infringement test, the NIR stent does not infringe because the thickness variations in the “wall surface” of the “tubular member” created by the protruding U-loops exceed the 100% outer limit of the Court’s claim construction. BSC Br. 15. JMOL of noninfringement is warranted because Cordis’s evidence about uniform strut thickness does not support the verdict, and also because Cordis did not challenge BSC’s evidence that the U-loops protrude by more than 100%. *Id.*

A. The Only Disputed Infringement Issue for the Jury Was to Identify the Structure on the NIR Stent That Corresponds to the “Wall Surface” of the “Tubular Member” That Is Required to Have a “Substantially Uniform Thickness.”

Cordis’s answering brief confirms that the only disputed infringement issue for the jury to decide was *identifying the structure* on the NIR stent that corresponds to the “wall surface” of the “tubular member” that is required by the claim to have a “substantially uniform thickness.” The jury had to choose between Cordis’s theory that the relevant structure is simply the metal of each individual strut or the starting material and BSC’s theory that the relevant structure is the tubular region that encompasses

the orientation of the protruding struts whose outer surface defines the “wall surface.” The jury’s decision on this disputed issue dictated the outcome of the ultimate infringement issue of whether the *thickness of that structure* was “substantially uniform,” because the evidence on *that* ultimate issue is *not* disputed: BSC does not dispute Cordis’s evidence that the thickness of the individual struts and the starting material of the NIR stent is uniform; Cordis does not dispute BSC’s evidence that the radial thickness of the tubular region that encompasses the orientation of the protruding U-loops on the NIR stent is not “substantially uniform” because many U-loops protrude by more than 100%. In other words, the jury had *only* to decide *what* should be measured; there was no dispute about the measurements.

B. Cordis’s Infringement Theory Equating the Strut Thickness with the Thickness of the “Wall Surface” Is Flawed Because It Is Based Solely on the Example of the Preferred Embodiment Made from a Preexisting Tube of Uniform Thickness.

Cordis does not dispute that the claim language requires the thickness of the “wall surface” of the “tubular member” to be “substantially uniform” and that this Court’s construction of the “substantially uniform thickness” limitation requires that thickness to be “largely or approximately uniform” and not to vary by 100% or more. Cordis Br. 3-4. Cordis’s position is that this claim language and construction simply require the thickness of each individual strut and the starting material to be “substantially uniform.” *Id.* The premise of Cordis’s argument is that the orientation of the metal does not matter in identifying the thickness of the “wall surface” and that the relevant thickness is simply the thickness of the metal, *i.e.*, the thickness of each individual strut and the starting material. *Id.* at 4 (“Because the wall is the metal that makes up the stent, the thickness of the wall is equal to the thickness of the metal.”).¹

The source of this premise is the description of the preferred embodiment of Figures 1A and 1B in the specification of the ’762 patent. In the preferred embodiment, the stent is cut from a preexisting tube with a uniform thickness. The struts have the same uniform thickness because they are oriented

¹ Cordis distorts Dr. Richter’s testimony when it argues that he agreed with Cordis at trial that the thickness of the “wall surface” is the thickness of the metal by testifying that “the metal is what defines the wall.” Cordis Br. 4, 8 (citing Tr. 848:17-22). It does not follow from Dr. Richter’s testimony that the metal defines the wall that the *orientation* of the metal is irrelevant. Indeed, Dr. Richter was clear in his testimony that the orientation of the protruding U-loops in the NIR stent defines the tubular region and affects the thickness of the “wall surface.” Tr. 870:10-21.

perfectly within the cylindrical plane of that tube when the stent is in the unexpanded state. '762 patent, col. 6, ll. 41-44. Based on the coincidence that the thickness of the "wall surface" happens to be equivalent to the thickness of the individual struts in the preferred embodiment, Cordis contends that the specification *defines* the thickness of the "wall surface" as the thickness of the individual struts for all stents. Cordis Br. 4, 10 (citing Tr. 426:9-27:23; '762 patent, col. 7, ll. 26-33). Cordis thus extracts a general definition from one example.

Not only is Cordis's logic flawed, its argument is at odds with the claim language, and with the clear statements in Cordis's own prosecution arguments and in the Federal Circuit's decision in the Cordis-AVE appeal about how to measure the thickness of the "wall surface" of a "tubular member" with struts that are not oriented perfectly within the cylindrical plane of a preexisting tube, but which instead protrude, as in the NIR stent and the prior art Ersek device. The claim language, Cordis's prosecution arguments and the Federal Circuit's decision each make clear that the thickness of the "wall surface" of the "tubular member" is the radial thickness of the tubular region that encompasses the orientation of the protruding struts whose outer surface defines the "wall surface," not the thickness of the individual struts or the starting material.

C. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Inconsistent with the Claim Language.

Although Cordis glosses over this point by ignoring the claim language and focusing instead on the term "wall" in the claim construction, Cordis does not dispute that the claim language states that it is the "wall surface disposed between the first and second ends" of the "tubular member," not the individual struts or the starting material, that must have a "substantially uniform thickness." BSC Br. 5. As the Court recognized when it defined the "wall surface" limitation to require that "[t]he outer surface of the tubular member must be disposed in a common cylindrical plane" (D.I. 1127 at 8), the "wall surface" is the outer surface of the struts that make up the tubular member. Accordingly, the term "wall surface" in the claim necessarily requires that the *thickness* of the "wall surface" take into account the placement and orientation of the struts whose outer surface defines the "wall surface." Where, as in the NIR stent, the struts are twisted or protrude relative to adjacent struts, the thickness of the "wall surface" is the radial

thickness of the tubular region that encompasses the orientation of the protruding struts whose outer surface defines the “wall surface,” not the thickness of the individual struts or the starting material.

D. Cordis’s Infringement Theory Equating the Strut Thickness with the Thickness of the “Wall Surface” Is Inconsistent with Its Own Prosecution Arguments in the Reexamination.

During the reexamination that it conducted in parallel with this litigation, Cordis told the Patent Office and the public that the thickness of the “wall surface” of a “tubular member” must take into account the orientation of the struts whose outer surface defines the “wall surface,” not simply the thickness of the individual struts or the starting material. BSC Br. 6-9. The examiner had advocated the very theory that Cordis presented at trial and in its brief when he initially concluded that the thickness of the wall of the “tubular member” of the Ersek device was uniform because the individual struts, although twisted out of the plane of the starting material, had the same uniform thickness as the starting material. BSC Br. 7-8 (citing PX-13, Tab 32 at 3009). In response, Cordis argued that the thickness of the “wall surface” of Ersek was not uniform even though the individual struts had the same uniform thickness as the starting material *precisely because* of the orientation of the protruding struts:

[T]he wall of [the Ersek] sleeve 16 is of varying thickness because the strands of the sleeve have twisted out of the plane of the starting material.

* * *

Clearly, the Ersek sleeve cannot be fairly said to have a wall surface with a “substantially uniform thickness.” ... *The strands extending between the bridge portions are twisted to have inwardly and outwardly projecting edges. This irregular and variable configuration is rough and is the antithesis of “substantially uniform thickness”*.

PX-13, Tab 36 at 3049, 3055 (emphasis added). In other words, Cordis told the Patent Office and the public that the thickness of the “wall surface” of a “tubular member” must take into account the orientation of the protruding struts, not just the thickness of the individual struts or the starting material, and that a device in which this thickness varies substantially because of the orientation of the protruding struts is *not* within the scope of the claimed invention. *Id.*

Cordis should not be permitted to argue that the infringement verdict is supported by substantial evidence based on a legal theory that is flatly inconsistent with its arguments to distinguish Ersek and secure allowance during the reexamination. On the basis on which Cordis argued at trial that the NIR

stent infringed, the Ersek device likewise satisfies the “substantially uniform thickness” limitation because the individual struts and the starting material of Ersek have a uniform thickness. Conversely, on the basis on which Cordis contended in the reexamination that the Ersek device does not meet the “substantially uniform thickness” limitation, the NIR stent likewise does not satisfy that limitation because the protruding U-loops produce variations in the thickness of the “wall surface” that exceed the 100% outer limit in the claim construction. This Court should not permit Cordis to have it both ways.

See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) (“Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.”).²

Cordis does not dispute *any* of this. Instead, Cordis defends the inconsistency between its arguments to the Patent Office and its infringement theory at trial and in its brief by arguing that the Federal Circuit already rejected BSC’s position during the Cordis-AVE appeal by holding that Cordis only disclaimed thickness variations of 100% or more based on Cordis’s distinction of the alleged double thickness at the bridge portions of the Ersek device. Cordis Br. 10-11. This is incorrect. The Federal Circuit did not address, much less reject, BSC’s position during the appeal for the simple reason that this issue was not before the Court. The issue in the appeal was whether this Court erred by ruling that certain prosecution arguments by Cordis distinguishing Ersek disclaimed coverage of thickness variations of 0.001 inch or more. The Federal Circuit agreed with Cordis that those prosecution arguments did not amount to a clear disclaimer, but did hold that certain other prosecution arguments by Cordis distinguishing Ersek based on the alleged double thickness at the bridge portions did amount to a disclaimer of variations of 100% or more. *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1361-62 (Fed. Cir. 2003). In other words, the Federal Circuit only addressed the *magnitude* of Cordis’s disclaimer of thickness variations—0.001 inch versus 100%—based on *certain* prosecution arguments. The Federal

² See also *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997) (“[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover.”); *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985) (“[T]he prosecution history ... exclude[s] any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.”); *Sutter v. Robinson*, 119 U.S. 530, 541 (1886) (“[The patentee] is not at liberty now to insist upon a construction of his patent which will include what he was expressly required to abandon and disavow as a condition of the grant.”).

Circuit did not address the impact of Cordis's *separate* prosecution arguments set forth above about *how* to measure the thickness of the "wall surface" of a "tubular member" with protruding struts, such as the Ersek device and the NIR stent. The struts of the accused AVE stents at issue in the appeal did not protrude and therefore did not present that issue, the parties to the appeal did not argue it, and the Federal Circuit accordingly did not address it, even implicitly.

E. Cordis's Infringement Theory Equating the Strut Thickness with the Thickness of the "Wall Surface" Is Inconsistent with the Federal Circuit's Decision in the Cordis-AVE Appeal.

During the Cordis-AVE appeal, the Federal Circuit also interpreted the claim language (without reference to any of Cordis's prosecution arguments). The Court explained that "according to the ... claims, it is the wall surface that needs to have a uniform thickness" and held that the thickness of the "wall surface" is the radial distance between the outer surface of the tubular member and the surface of an imaginary cylinder that would fit inside the tubular member:

The district court described the wall surface by stating that "[t]he outer surface of the tubular member must be disposed in a common cylindrical plane." That common "cylindrical plane" is formed by an imaginary circle that intersects with the outermost point of each round strut. The thickness of the wall is equal to ... the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member.

Cordis, 339 F.3d at 1362; BSC Br. 5-6.

Cordis's argument equating the thickness of the "wall surface" of the "tubular member" with the thickness of the individual struts and the starting material is inconsistent with this holding by the Federal Circuit. Under the Federal Circuit's test, the thickness of the "wall surface" is the radial distance between the outer surface of the struts that define the "wall surface" and an imaginary cylinder inside the tubular member. In a stent such as the NIR stent, which is not cut from a preexisting tube but instead has struts that protrude at an angle, this thickness depends on the orientation of the protruding struts which define the outer surface that forms the "wall surface."

Cordis does not dispute BSC's interpretation of the Federal Circuit's holding or that, under that holding, Cordis's evidence about individual strut thickness is not probative of the thickness of the "wall surface" of the "tubular member" of the NIR stent. Cordis's only response is that the Federal Circuit's

holding can be ignored because of this Court's *in limine* ruling before trial that the Federal Circuit did not mandate a particular method for measuring the thickness of the "wall surface." Cordis Br. 9-10 (citing D.I. 1337 at 5-6). BSC submits that the Court erred in excluding the Federal Circuit's explanation of how to measure thickness, which is the law of the case that binds this Court on remand, and that it would be error to continue to ignore it as Cordis urges. *AFG Indus., Inc. v. Cardinal IG Co.*, 375 F.3d 1367, 1372 (Fed. Cir. 2004); *Bankers Trust Co. v. Bethlehem Steel Corp.*, 761 F.2d 943, 949 (3d Cir. 1985).

F. Cordis's Criticism of BSC's Noninfringement Defense Based on the Protruding U-Loops of the NIR Stent Is Inconsistent with Cordis's Own Prosecution Arguments, with the Claim Language, and with the Federal Circuit's Decision.

Cordis challenges BSC's noninfringement defense based on the protruding U-loops of the NIR stent by arguing that BSC improperly confuses the height of the U-loops with the thickness of the wall by including the "empty space" beneath the U-loops (Cordis Br. 6-9), and thereby confuses the "wall surface" limitation with the "substantially uniform thickness" limitation (Cordis Br. 11-12). However, BSC's noninfringement theory—which Cordis denigrates as a "game," a "ruse" and a "trick" designed to deceive the jury (Cordis Br. 7-8)—is *precisely the same theory* that Cordis applied when it told the Patent Office during the reexamination why the "wall surface" of the "tubular member" of the Ersek device does not have a uniform thickness, and is also the theory that is mandated both by the claim language and by the Federal Circuit's decision in the Cordis-AVE appeal.

Just as BSC argued at trial with respect to the NIR stent, Cordis argued during the reexamination that the thickness of the "wall surface" of the "tubular member" of the Ersek device is not uniform because the struts protrude. PX-13, Tab 36 at 3049, 3055. Cordis's method of measuring the thickness of the "wall surface" of Ersek during the reexamination based on the orientation of the twisted struts necessarily included the "empty space" under the protruding struts. Otherwise, the thickness of the "wall surface" of Ersek would simply be the uniform thickness of the struts and the starting material—the position that the examiner initially took but which Cordis refuted.³

³ Cordis's separate argument to the Patent Office and to the Federal Circuit that Ersek has a double thickness at each bridge portion (Cordis Br. 11) also necessarily includes the "empty space" under the struts as part of the thickness of the "wall surface" because, as Dr. Snyder explained at trial, the struts

Similarly, since the use of the term “wall surface” in the claim necessarily requires that the thickness of the “wall surface” take into account the placement and orientation of the struts whose outer surface defines the “wall surface,” this thickness necessarily includes the “empty space” under the protruding struts. Finally, the Federal Circuit’s method of measuring the thickness of the “wall surface” in the Cordis-AVE appeal, based on measuring the radial distance between the outer surface of the protruding struts that define the “wall surface” and an imaginary cylinder inside the tubular member, also necessarily includes the “empty space” under the protruding struts.

Apart from this flawed attack on BSC’s noninfringement defense, Cordis did not challenge at trial or in its brief BSC’s evidence that the U-loops of the NIR stent protrude by more than the 100% outer limit in the Court’s claim construction.⁴ Under the proper infringement test, the thickness of the “wall surface” of the “tubular member” of the NIR stent is not “substantially uniform” because of the thickness variations created by these protruding U-loops. JMOL of noninfringement is warranted because Cordis’s legally irrelevant evidence that the individual struts of the NIR stent are uniformly thick does not support the verdict. JMOL is also warranted because Cordis did not challenge BSC’s evidence.

II. A New Infringement Trial Is Warranted Because of Prejudicial Errors That Very Likely Affected the Verdict.

A. It Was Prejudicial Error to Instruct the Jury Wrongly During Deliberations That the “Wall Surface” Limitation Was Not In Dispute When Identifying the Structure That Corresponded to the “Wall Surface” Was Disputed and Critical to Whether the “Substantially Uniform Thickness” Limitation Was Met.

The Court’s instruction to the jury during deliberations that the “wall surface” limitation was not in dispute and that the only limitation in dispute was the “substantially uniform thickness” limitation⁵ (in response to the jury’s question about the meaning of the “wall surface” limitation and the Court’s

in expanded metal never rotate all the way to 90 degrees, so there is never a true double thickness of metal measured along the radial direction. Tr. 897:20-98:2; 921:8-21.

⁴ Cordis’s conclusory and unsupported assertion that the U-loops of the NIR stent only “protrude a tiny amount” (Cordis Br. 6) is belied by BSC’s undisputed evidence that many U-loops protrude by more than the 100% outer limit in the Court’s construction. Tr. 968:7-69:15.

⁵ After BSC filed its brief, the Court disclosed the precise language of its instruction, which stated: “Let me remind you that the ‘wall surface’ limitation is not in dispute in this case. The only limitation in dispute in this case is the ‘substantially uniform thickness’ limitation.” D.I. 1403.

construction of that limitation) was very prejudicial because the Court's instruction was false in two critical respects. BSC Br. 16-20.

First, the instruction that the "wall surface" limitation was not in dispute was false because, even though BSC had stipulated for purposes of trial that the NIR stent *satisfied* the "wall surface" limitation either literally *or by equivalents*, the "wall surface" *limitation* was very much in dispute. As explained above, the only disputed issue for the jury to decide was to *identify the structure* on the NIR stent that corresponded to the "wall surface" of the "tubular member" that is required by the claim to have a "substantially uniform thickness," because the jury's decision on this issue dictated the outcome of the ultimate and undisputed infringement issue of whether the thickness of that structure was "substantially uniform." By effectively instructing the jury to ignore the "wall surface" limitation and the Court's construction of that limitation and to focus exclusively on the "substantially uniform thickness" limitation, the Court bolstered Cordis's infringement case based on strut thickness by diverting the jury from this critical issue of determining *what* structure had to have a "substantially uniform thickness."

Second, the instruction was also false because it improperly suggested to the jury that the outer surface of the NIR stent *literally* is "disposed in a common cylindrical plane" under the Court's construction of "wall surface" even though that is plainly not true and is vigorously disputed by BSC, and even though BSC had only stipulated, based on the prior verdict of infringement only *by equivalents*, that the NIR stent satisfies the "wall surface" limitation either literally *or by equivalents*. D.I. 1310, Tab 1, ¶ 9.⁶ The Court's instruction to the jury, in the absence of any instruction about the doctrine of equivalents or about the qualified nature of BSC's stipulation, bolstered Cordis's infringement case by improperly suggesting to the jury that there was literal infringement of the "wall surface" limitation, and therefore

⁶ Not only has BSC never admitted that the NIR stent *literally* satisfies the "wall surface" limitation, but there has been no finding of literal infringement of that limitation by any jury or court. Even this Court's prior decision after the prior trial in 2000 that there was sufficient evidence to support a finding of literal infringement of that limitation had to be based on Cordis's "alternative" tubular member theory at that trial, which ignored the protruding U-loops by treating each C-region of the NIR stent as a "tubular member." D.I. 1127 at 45. If the entire NIR stent is considered to be the "tubular member," as Cordis conceded for the recent trial, the NIR stent plainly does not literally satisfy the "wall surface" limitation because the protruding U-loops are not literally "disposed in a common cylindrical plane."

that the protruding U-loops were unimportant and irrelevant. This instruction was very prejudicial because these protrusions were the focus of BSC's noninfringement case and were plainly and starkly evident in the photographs of the NIR stent in evidence (some of which the jury had asked to see earlier during deliberations). BSC Br. 15, 18-20; Tr. 1372:5-75:23. It is hardly surprising that shortly after receiving the Court's instruction, the jury, which had previously been deliberating for several hours, promptly returned an infringement verdict for Cordis.

Cordis does not dispute *any* of this. Instead, Cordis argues that BSC's stipulation for trial that the NIR stent satisfies the "wall surface" limitation *at least by equivalents* defeats BSC's new trial argument because the stipulation is "identical in substance to the instruction that BSC now attacks as prejudicial error." Cordis Br. 13-15 (citing D.I. 1310, Tab 1, ¶ 9; Tr. 821:9-13; 832:9-833:11; 847:11-19; 848:5-11). Cordis is incorrect because BSC's stipulation and the Court's instruction that "the 'wall surface' limitation [was] not in dispute" are critically different. As explained above, even though BSC did not dispute that the NIR stent satisfied the "wall surface" limitation *at least by equivalents*, BSC has always disputed that the NIR stent *literally* satisfies that limitation. Moreover, the "wall surface" *limitation* was *very much in dispute* at trial because BSC and Cordis vigorously disputed *which structure* on the NIR stent corresponded to the "wall surface" that is required by the claim to have a "substantially uniform thickness." The Court's instruction to the jury went far beyond BSC's stipulation, and appears to have steered the verdict in Cordis's favor. BSC should be granted a new trial.⁷

B. It Was Reversible Error for Cordis to Treat Undesignated Impeachment Deposition Testimony as Substantive Evidence to Mislead the Jury into Believing That BSC Had Admitted Infringement.

It was reversible error for Cordis to treat undesignated and out-of-context impeachment deposition testimony by Mr. Brown and Dr. Low as substantive evidence during closing arguments to mislead the jury into believing that BSC admitted infringement. BSC Br. 20-22.

⁷ In view of the Court's April 29, 2005 letter enclosing the Court's note to the jury (D.I. 1402, 1403), BSC has respectfully withdrawn its separate argument that the failure to keep a written record of the Court's instruction was prejudicial error (BSC Br. 20-22) and again apologizes for misunderstanding the advice from the Court's chambers.

Although Cordis does not dispute that Dr. Low's testimony was introduced solely for impeachment, Cordis argues that Mr. Brown's testimony (from other cases) was admitted as substantive evidence as a party admission under Fed. R. Evid. 801(d)(2)(D). Cordis Br. 16-17. This is incorrect. Mr. Brown's testimony was never admitted into evidence. Although Cordis offered the testimony as an admission (and BSC objected), the Court never admitted the evidence and only permitted it to be used for impeachment. Tr. 863:6-64:19; 1230:20-31:4. In any event, whether Mr. Brown's testimony was admissible under Rule 801(d)(2)(D) does not change the fact that Cordis did not comply with the separate requirements of Fed. R. Civ. P. 32(a)(4) and the pretrial order, under which Cordis was obliged to provide BSC with five days' notice of its intention to introduce this testimony so that BSC could object and introduce other portions of the deposition "which ought in fairness" to be introduced. Fed. R. Civ. P. 32(a)(4); D.I. 1310, Tab 1, ¶ VII.3. These requirements exist to prevent the kind of misleading presentation that occurred here:

The touchstone of [Fed. R. Civ. P.] 32(a)(4) and [Fed. R. Evid.] 106 is "fairness." Each of these rules is born of the legitimate concern with "misleading impressions created by taking statements in documents or recordings out of context." Unlike [Fed. R. Evid.] 801(d)(2), which is concerned with whether a statement constitutes hearsay for purposes of admissibility, Rules 32(a)(4) and 106 assume the admissibility of a written statement, and ask, in turn, whether fairness demands that other parts of the writing be admitted to provide context and avoid misimpressions.

Crowley v. Chait, Civ. No. 85-2441(HAA), 2004 U.S. Dist. LEXIS 27235, at *67 (D.N.J. Dec. 27, 2004) (Ex. A) (citations omitted).⁸ Cordis does not dispute that it violated both Rule 32(a)(4) and the pretrial order and that this violation prevented BSC from eliminating or mitigating the impact of Cordis's misleading and out-of-context use of the testimony.

Cordis does not dispute that its use of Mr. Brown's testimony about the flaring of the U-loops of the NIR stent was misleading and prejudicial. However, Cordis argues that Mr. Brown's and Dr. Low's testimony about strut thickness were merely cumulative and not prejudicial. Cordis Br. 16-18. Cordis is

⁸ The cases Cordis cites (Cordis Br. 16-17) recognize that fairness requires that the opposing party be given an opportunity to counter-designate portions of testimony sought to be introduced. See, e.g., *Tracinda Corp. v. DaimlerChrysler AG*, C.A. No. 00-993-JJF, 2005 WL 730322, at *18 (D. Del. Mar. 30, 2004); *Globe Savings Bank, F.S.B. v. United States*, 61 Fed. Cl. 91, 99 (Ct. Cl. 2004); *Coleman v. Wilson*, 912 F. Supp. 1282, 1295 (E.D. Cal. 1995).

incorrect. This testimony was not cumulative and was very prejudicial because Cordis used misleading excerpts out of context to deceive the jury into believing that, unlike Dr. Snyder, Mr. Brown and Dr. Low had agreed with Cordis's argument that the thickness of the struts is the same as the thickness of the "wall surface" and therefore that the NIR stent infringed, when neither of them had testified to that effect.

Cordis's argument that it was proper to refer and comment on this impeachment material during closing arguments because it was "part of the record" (Cordis Br. 17) is also incorrect. A new trial is warranted where a closing argument refers to prejudicial extraneous evidence that goes beyond the admitted evidence. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 210 (3d Cir. 1992); *Ayoub v. H.N. Spencer*, 550 F.2d 164, 170-71 (3d Cir. 1977). The only admitted evidence to which Cordis's counsel should have referred during his closing argument was Dr. Snyder's and Dr. Richter's testimony—both disagreeing with the impeachment testimony—not Mr. Brown's or Dr. Low's testimony or counsel's questions quoting from it. *United States v. Barber*, 442 F.2d 517, 523 (3d Cir. 1971); *United States v. Quintero*, 38 F.3d 1317, 1340 (3d Cir. 1994).

Cordis's use of this misleading impeachment material during closing arguments as though it was admitted substantive evidence was very prejudicial because it gave the jury the false impression that Mr. Brown and Dr. Low had agreed with Cordis that the strut thickness is the thickness of the "wall surface" and therefore that the NIR stent infringed, when neither of them had testified to that effect. This alone warrants a new trial.

III. JMOL of Invalidity Is Warranted Because Cordis's Evidence of the Nonobviousness of the Intraluminal Method Was Legally Irrelevant and Does Not Support the Verdict, and BSC's Evidence of the Obviousness of the Claimed Device Was Clear and Convincing and Not Challenged by Cordis.

JMOL of invalidity for obviousness of claim 23 is warranted because Cordis's evidence that the noninvasive method of intraluminally delivering and expanding a stent on a balloon is not obvious as compared to the surgical method of Ersek does not legally support the nonobviousness verdict, and Cordis did not challenge BSC's clear and convincing evidence that the device of claim 23 would have

been obvious in view of the prior art Ersek device.⁹

A. The Validity of Claim 23 Depends on the Nonobviousness of the Claimed Structure Because the Claim Is Directed to a Device, Not to a Device That Must Be Used in a Particular Method.

Like its infringement theory, Cordis's nonobviousness theory is also based on a flawed premise: that claim 23 is directed to a graft that must be used in a method of intraluminal delivery and expansion on a balloon. Based on this premise, Cordis offered irrelevant evidence of the nonobviousness of using the graft to perform that method as compared to the invasive surgical method of Ersek. Cordis Br. 18-29. Cordis's evidence does not support the verdict because the claim is directed to a device, not to a device that must be used in a particular method. The claim only describes the structure and properties of the graft, not how it must be used. BSC Br. 27-28.¹⁰ Moreover, the term "intraluminal" in the preamble is not a claim limitation requiring the claimed graft to be used in a method involving intraluminal delivery as Cordis argues (Cordis Br. 18-22) because "[the] patentee [has] define[d] a structurally complete invention in the claim body and use[d] the preamble only to state a purpose or intended use for the invention." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).¹¹ Therefore, the validity of the claim

⁹ Cordis's argument that the prior nonobviousness findings by the Cordis-ACS arbitration panel and the Cordis-AVE jury are a "red flag warning" against granting BSC JMOL of obviousness (Cordis Br. 18) is incorrect. The case on which Cordis relies addresses the deferential weight to which prior court decisions should be afforded as legal precedent, not prior jury verdicts or arbitration panel findings. *See Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1569-70 (Fed. Cir. 1993) (prior district court decision affirmed on appeal is entitled to weight as legal precedent). The prior arbitration and jury findings are irrelevant to whether JMOL is appropriate on the record developed at the BSC trial. *See Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 627 (Fed. Cir. 1984); *see also Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1091 (Fed. Cir. 1987); 35 U.S.C. § 294(c).

¹⁰ In particular, contrary to Cordis's argument (Cordis Br. 22), claim 23 only states that the tubular member must have a first diameter which will "permit intraluminal delivery of the tubular member into a body passageway having a lumen," not that the tubular member must be intraluminally delivered into a body passageway. Other claims, which were not in suit, such as claim 1, are directed to the method of intraluminal delivery about which Cordis offered evidence at trial and which is described in the excerpts from the specification to which Cordis refers. Cordis Br. 19-20 (citing '762 patent, col. 1, ll. 19-25, 28-37).

¹¹ Unlike *Catalina*, each case on which Cordis relies to argue that the preamble term "intraluminal" limits the claim (Cordis Br. 20-22) is distinguishable. In *Pitney-Bowes Co. v. Hewlett-Packard, Inc.*, 182 F.3d 1298 (Fed. Cir. 1999), the preamble terms "generated shapes" and "spots" were necessary to understand the body of the claim. *Id.* at 1306. In *In re Cruciferous Sprout Litig.*, 301 F.3d

depends on the nonobviousness of “the claimed structure, not on the use or purpose of that structure.” *Catalina*, 289 F.3d at 809 (citing *In re Gardiner*, 171 F.2d 313, 315-16 (CCPA 1948)).¹² Accordingly, the obviousness issue at trial should have been whether the *device* of claim 23 was obvious as compared to the Ersek *device*, not whether the intraluminal *method* of delivering and expanding a stent on a balloon was obvious as compared to the invasive surgical *method* of Ersek.

B. Cordis’s Evidence Does Not Support the Verdict Because It Does Not Relate to the Nonobviousness of the Structure of the Claimed Device.

The evidence to which Cordis points in its brief as substantial evidence does not support the verdict because it is directed to the nonobviousness of the method of intraluminally delivering and expanding a stent on a balloon as compared to the invasive surgical method of Ersek, not to the nonobviousness of the claimed device as compared to the Ersek device.

First, Cordis’s argument that there is substantial evidence that the Ersek patent is not within the scope and content of the prior art (Cordis Br. 19) is based on differences between the intraluminal method of Palmaz and the surgical method of Ersek, not on any differences between the two devices. Since claim 23 is directed to a simple mechanical structure, the scope and content of the prior art includes similar structures in other fields, such as the almost identical structure of the Ersek sleeve. *See Stevenson v. Int’l*

1343 (Fed. Cir. 2002), the patentee relied on the preamble term “rich in glucosinolates” to distinguish prior art during prosecution. *Id.* 1347-48. In *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823 (Fed. Cir. 2003), the patentee relied on the preamble term “forwarding device” to distinguish prior art during prosecution and that term also recited “additional structure or steps underscored as important by the specification.” *Id.* at 834-35 (quoting *Catalina*, 289 F.3d at 808 (emphasis added)). In *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303 (Fed. Cir. 2004), the term “blown-film” appeared in the preamble of every claim in the patent. *Id.* at 1310. Finally, in *Corning Glass Works, Inc. v. Sumitomo Elec. USA, Inc.*, 868 F.2d 1251 (Fed. Cir. 1989), the preamble term “optical waveguide” defined the function of the claimed structure. *Id.* at 1257.

In contrast, Cordis did not rely on the term “intraluminal” in the preamble to distinguish claim 23 from the prior art. Even though Cordis discussed the intended use of the device in connection with other claims, including method claims, Cordis amended claim 23 to add “smooth surface” and relied on that amendment and other *structural* limitations, such as “wall surface” and “substantially uniform thickness,” to distinguish the prior art. *See* PX-13, Tab 36 at 3054-58.

¹² Cordis’s argument that it is too late for BSC to contend that the term “intraluminal” in the preamble does not limit the claim (Cordis Br. 22) is specious. Even though Cordis never requested the Court to construe the preamble term “intraluminal” as a claim limitation and the Court never did so, Cordis treated the term as a claim limitation at trial in order to distinguish Ersek. Tr. 501:20-02:11. BSC is simply responding to Cordis’s newly minted trial theory.

Trade Comm., 612 F.2d 546, 550 (CCPA 1979) (“In a simple mechanical invention a broad spectrum of prior art must be explored.”); *Toro Co. v. Textron, Inc.*, 499 F. Supp. 241, 248 (D. Del. 1980) (“[P]rior art” ... with respect to a simple mechanical device utilizing universally known principles permits referring to the field of mechanics itself.”); *see also In re Paulsen*, 30 F.3d 1475, 1481-82 (Fed. Cir. 1994).

Second, Cordis’s argument that there is substantial evidence that the differences between claim 23 and the Ersek patent are “pervasive,” “numerous” and “significant” (Cordis Br. 22-25) is also based primarily on differences between the intraluminal method of Palmaz and the surgical method of Ersek, not on any differences between the two devices. To the extent that Cordis actually points to structural differences between the two devices, Cordis did not seriously challenge BSC’s evidence that those differences are minor and that one of ordinary skill would have been motivated to modify the Ersek device to arrive at the claimed device.¹³

Third, Cordis’s argument that there is substantial evidence of secondary considerations (Cordis Br. 25-29) ignores the fact that Cordis’s evidence related primarily to the nonobviousness of the method of intraluminally delivering and expanding a stent on a balloon, not of the claimed device.¹⁴ Despite Cordis’s conclusory assertion to the contrary (Cordis Br. 29), there is no nexus between Cordis’s evidence and the claimed invention. *See Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988).¹⁵

¹³ Cordis’s conclusory argument that no such motivation existed (Cordis Br. 24-25) ignores Dr. Snyder’s unchallenged evidence of several sources of a motivation, such as the knowledge of those of ordinary skill and the prior art, including the Palmaz abstract and the Ersek patent itself, which teaches making the Ersek device smoother to facilitate delivery. Tr. 948:20-57:13.

¹⁴ Cordis’s evidence of long felt need, failure by others and praise (Cordis Br. 25-27) related to intraluminally delivering and expanding a stent on a balloon to improve balloon angioplasty, not to the claimed device. Cordis’s evidence of skepticism (Cordis Br. 26) related to thrombosis (which Dr. Colombo, not Dr. Palmaz, solved (Tr. 194:12-98:5)) and the mechanical failure of the Shiley heart valve (which was made of a brittle metal and repeatedly opened and closed as the heart beat (Tr. 1065:5-71:24)), not to the claimed device. Finally, Cordis’s evidence of the commercial success of Cordis’s stents (Cordis Br. 26-27) related to the method of intraluminal delivery and expansion on a balloon, to flexibility (introduced by Dr. Schatz), and to the benefits of drug elution, not to the claimed device.

¹⁵ Cordis’s feigned offence at Dr. Snyder’s and Dr. Richter’s testimony about the lack of relevance of praise for Dr. Palmaz (Cordis Br. 28) rings hollow given Cordis’s counsel’s *ad hominem* attacks against not only Dr. Snyder and Dr. Richter but also Mr. LaViolette, Dr. Low, BSC and BSC’s counsel. *See* Tr. 1224:3-4; 1292:18-95:25; 1302:1-7; 1320:1-25; 1323:23-24:2; 1330:7-12. Cordis’s argument also ignores the fact that Dr. Snyder’s and Dr. Richter’s testimony addressed the lack of nexus between this praise and the claim. Tr. 758:3-20; 958:21-59:8; 1073:17-76:17.

Apart from Cordis's irrelevant evidence about the nonobviousness of the method of intraluminally delivering and expanding a stent on a balloon as compared to the invasive surgical method of Ersek, Cordis did not offer any evidence at trial to support the verdict. JMOL of invalidity for obviousness is warranted because Cordis did not challenge BSC's clear and convincing evidence that the claimed device is almost identical to the Ersek device, that the differences between the devices are so trivial that the claimed device would have been obvious, and that one of ordinary skill in the art would have been motivated to modify the Ersek device to arrive at the claimed device. BSC Br. 28.

IV. A New Obviousness Trial Is Warranted Because of Prejudicial Errors That Very Likely Affected the Verdict.

A. It Was Prejudicial Error to Prevent BSC from Addressing the Method Claims to Which Cordis's Nonobviousness Evidence Was Related.

It was prejudicial error to permit Cordis to present extensive evidence about the nonobviousness of the method of intraluminally delivering and expanding a stent on a balloon covered by claims not in suit as though it related to the obviousness of the device of claim 23, while simultaneously preventing BSC from drawing the jury's attention to those unasserted claims. BSC Br. 33. Cordis's conclusory and unexplained argument that this would have confused the jury (Cordis Br. 30) should be rejected because BSC's evidence would have ameliorated the confusion caused by Cordis's effort to distract the jury from the obviousness of the device of the sole claim in suit, not exacerbated it. BSC Br. 33.

B. It Was Prejudicial Error to Prevent BSC from Rebutting Any Nexus Between Cordis's Evidence About Industry Success and the Rigid Claimed Stent with Cordis's Admission During "Project Olive" about the Key Importance of Flexibility.

It was prejudicial error to permit Cordis to proclaim that the success of the entire stent industry rested on the features of the claimed device while simultaneously preventing BSC from challenging the alleged nexus between that success and the claim by introducing Cordis's admission during "Project Olive" that flexibility, which is not a feature of the claim, was key to that success. BSC Br. 33-36.

Cordis's argument that this evidence was cumulative of BSC's own witnesses' testimony about the flexibility and superiority of the NIR stent (Cordis Br. 30-32) is wrong because it ignores the fact that the excluded "Project Olive" evidence includes *admissions by Cordis* about the importance of flexibility

to success that flatly contradict Cordis's story to the jury. *See, e.g., Beck v. Haik*, 377 F.3d 624, 638-40 (6th Cir. 2004). Cordis's argument that the excluded evidence was prejudicial and confusing because Cordis did not assert infringement under the doctrine of equivalents at trial (Cordis Br. 32) is unintelligible. Cordis does not dispute that the excluded evidence was squarely relevant to whether there was a nexus between Cordis's evidence of success and the claimed device for purposes of obviousness.

C. It Was Prejudicial Error to Permit Cordis to Treat Admittedly Misleading Impeachment Material as Substantive Evidence to Mislead the Jury into Believing That the Ersek Sleeve Is Like a "Stapler."

It was prejudicial error to allow Cordis to use Dr. Ersek's curriculum vitae and out-of-context testimony by Dr. Heuser from the Cordis-AVE trial to mislead the jury into believing that, unlike Dr. Snyder, they both considered the Ersek sleeve to be like a "stapler," when, as Cordis and its counsel well knew, both of them had actually testified that they did not.

Apart from two legally unsupported and conclusory arguments, Cordis does not seriously dispute BSC's arguments in favor of a new trial.¹⁶

Cordis's argument that there was no need to consider the probative value or prejudice of this material because it was only introduced for impeachment and "an expert can be impeached by anything" (Cordis Br. 33 n.1) is incorrect. As BSC argued when it objected at trial (Tr. 1053:5-54:14), the use of material for impeachment is subject to Fed. R. Evid. 403 and should not be permitted if its probative value is outweighed by unfair prejudice. *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 415-16

¹⁶ Cordis does not dispute that Dr. Ersek's description of his patent in his curriculum vitae and Dr. Heuser's misleading and out-of-context testimony about that description had absolutely no probative value because the Court had already ruled that Dr. Ersek did not qualify as one of ordinary skill. BSC Br. 37. Cordis also does not dispute that Cordis misled both the Court and the jury into believing that Dr. Ersek and Dr. Heuser considered the Ersek sleeve to be like a "stapler" when both of them had actually testified at the AVE trial that they did not. *See* BSC Br. 38 (citing 3/9/05 Tr. 1251:13-14 (Ersek: "I never meant to say it was a stapler.")); 3/10/05 Tr. 1601:16-17 (Heuser: "I don't agree that it was a staple-like device."')). Moreover, Cordis does not dispute that it was very prejudicial for Cordis to unfairly isolate and disparage Dr. Snyder during closing arguments by misleading the jury into thinking that he was the only person who did not consider the Ersek sleeve to be like a "stapler." BSC Br. 39 (citing Tr. 1302:1-7; 1320:23-25; 1323:23-25). Finally, Cordis also does not dispute that it was very prejudicial during closing arguments for Cordis to treat Dr. Ersek's legally irrelevant description of his patent in his curriculum vitae, which had only been introduced for impeachment, as substantive evidence of the disclosure of that prior art patent to which the jury should give weight. BSC Br. 38-39 (citing Tr. 1320:3-13; 1323:15-20).

(3d Cir. 2002).

Cordis's argument that it was proper to refer and comment on this impeachment material during closing arguments because it was part of the trial transcript (Cordis Br. 33) is also incorrect. A new trial is warranted where a closing argument refers to prejudicial extraneous evidence that goes beyond the admitted evidence. *Fineman*, 980 F.2d at 210; *Ayoub*, 550 F.2d at 170-71. Even if it had been proper to use this material for impeachment, the only admitted evidence to which Cordis's counsel should have referred during closing arguments was Dr. Snyder's testimony disagreeing with Dr. Ersek's curriculum vitae and Dr. Heuser's testimony, not the impeachment material or counsel's questions quoting from it. *Barber*, 442 F.2d at 523; *Quintero*, 38 F.3d at 1340. Cordis's use of this legally irrelevant impeachment material during closing arguments as though it was admitted substantive evidence was very prejudicial and warrants a new trial.

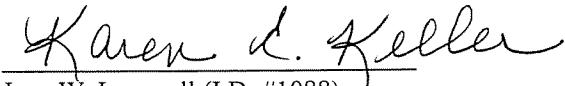
CONCLUSION

For the reasons set forth above and in BSC's opening brief, BSC respectfully urges the Court to grant BSC's renewed motion for JMOL, and, in the alternative, for a new trial.

Respectfully submitted,

May 25, 2005

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on May 25, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on May 25, 2005, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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